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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,513	02/28/2000	Joseph Chappell	07678/011003	8901
21559	7590	03/04/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			KALLIS, RUSSELL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/514,513

### Applicant(s)

CHAPPELL ET AL.

### Examiner

Russell Kallis

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-15 are pending. Claims 1-15 are examined.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1-15 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/30/2003. Applicant's arguments filed 11/26/2003 have been considered but are not deemed persuasive.

Applicant asserts that isoprenoid synthases comprise multiple protein families, ranging from plants to humans to yeast, that consist of different combinations of functional protein domains that catalyze the synthesis of different chemical compounds and further recites that TEAS from tobacco, HVS from henbane, CPP synthase and FPP synthase from sagebrush have been isolated and shown to have the five conserved regions that catalyze chain elongation (response pages 3-4).

Applicant further asserts that the published work of Tamer *et al.* (Arch. Biochem. and Biophys., 411 (2003) pp. 196-203) and Schalk *et al.*, PNAS, 97; (22): pp. 11948-11953 shows

that the authors identified the conserved domains and were able to reorganize the conserved domains to produce novel chimeric isoprenoid synthases having altered activities (response pages 4 and 5).

The publication date of the cited reference is well after the date of the priority claim (4/12/1996) of the instant application and does not support Applicant's assertion that the reference provides a description of the broad the broadly claimed genus of chimeric isoprenoid synthase polypeptides and polynucleotides encoding said polypeptides.

Applicant asserts that the examiner pointed out that the specification provided several examples of chimeric isoprenoid synthases that were generated using publicly available sequence information and that the claims are no broader than the written description (response page 6).

Based upon the disclosure of TEAS and HVS, there is insufficient relevant identifying characteristics to allow one skilled in the art to completely determine the structure of the broadly claimed genus of chimeric isoprenoid synthases, that synthesizes a reaction product not produced by the non-chimeric isoprenoid synthase or at least two reaction products not normally produced together by the wild type or non-chimeric isoprenoid synthase at the time of the claimed priority date.

3. Claims 1-15 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plant cells and plants comprising chimeric variants of TEAS and HVS, (CH1-CH14), and quiescent synthases, does not reasonably provide enablement for plant cells and plants comprising any chimeric isoprenoid synthase having an asymmetrically positioned homologous domain that synthesizes a reaction product not produced by the non-chimeric isoprenoid synthase or at least two reaction products not normally produced together by

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the wild type or non-chimeric isoprenoid synthase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/30/2003. Applicant's arguments filed 11/26/2003 have been considered but are not deemed persuasive.

Applicant asserts that there may be some isoprenoid synthases that lack a given domain but that this would not prevent one from making chimeric polypeptides (response page 7, lines 10-13) and that there is no evidence that the conserved domains from different plants will not tolerate chimerization (response page 7 last paragraph).

The evidence is provided in Tamer *et al.* (Arch. Biochem. and Biophys., 411 (2003) pp. 196-203; see Abstract lines 10-12) and Schalk *et al.* (PNAS, 97; (22): pp. 11948-11953; page 11950, column 2 3<sup>rd</sup> full paragraph; and page 11951, column 1 2<sup>nd</sup> full paragraph) where the authors state that many of the chimeras were inactive either because of improper folding or resulted in inactive enzymes although they were properly folded. Clearly, because the specification does not provide adequate guidance, one of skill in the art would be required to practice undue trial and error experimentation to find an operable embodiment.

Further, Applicant's has asserted repeatedly that the submitted journal references show domain swapping of conserved regions resulted in altered activity and claims an asymmetrically positioned homologous domain that catalyzes an isoprenoid reaction product not produced by the naturally occurring site. This is not made evident by Schalk *et al.* (PNAS, 97; (22): pp. 11948-11953), where the author's remarks are directed towards the involvement of specific residues and the importance of progressively placed directed mutations into a conserved region and not

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asymmetrically positioned domains as being determinant for changes in product formation (Erickson H. *et al.* J. Am. Chem. Soc.; 2003 vol. 125, pp. 6886-6888; see page 6886, column 2 lines 27-33).

Furthermore, the publication dates for the submitted journal articles are well after the claim for priority of 4/12/1996 and thus do not support the claim for enablement at the effective time of filing.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.  
February 18, 2004



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